PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	KUMAR, Vijay
SERIAL NO	:	10/007,866
FILED	:	December 6, 2001
TITLE	:	BIODEGRADABLE OXIDIZED CELLULOSE ESTERS
Grp./A.U.	:	1623
Examiner	:	White, E.
Conf. No.	:	6560
Docket No.	:	P04829US1

SUPPLEMENTAL RULE 132 DECLARATION OF DR. VIJAY KUMAR

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Sir:

I, Dr. Vijay Kumar, hereby declare the following:

1. I am a co-inventor of the invention set forth in Serial No. 10/007,866.

2. The present invention describes for the first time the synthesis of biodegradable oxidized cellulose esters.

3. In comparison to previously made oxidized ceullulose esters, the products of this invention offer a new class of biodegradable polymers that undergo hydrolysis by enzymatic and/or chemical means *in vivo* and *in vitro*. They may therefore be used as biomaterials and as drug carriers in medicine, pharmaceutics, agriculture, and veterinary fields.

4. In addition, these oxidized cellulose esters are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer.

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5. While others in the art have successfully synthesized carboxylated cellulose esters, such compounds are not biodegradable.

6. Studies show that the carboxyl content and degree of polymerization (DP) of oxidized cellulose play important roles in the degradation of oxidized cellulose *in vitro* and *in vivo*. In general, the higher the carboxyl content, or the lower the DP, the faster the rate of degradation of oxidized cellulose.

7. Compared to other biodegradable polymers, oxidized cellulose has received little consideration as a potential biomaterial or drug carrier. This is because it is practically insoluble in organic solvents and water, and hence, poses little or no formulation flexibility.

8. Recently, U.S. Patent No. 5,973,139 (Lee et al.) disclosed a process for producing carboxylated cellulose esters using oxidized cellulose materials containing about 0.14-0.3% w/w of carboxylic content. In this process, the starting cellulose source is first esterified and then hydrolyzed to give the product. The carboxylated cellulose esters prepared by this method are useful in the development of coating formulations that can be applied to paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

9. Another previous method in the art for preparing carboxylated cellulose esters uses cellulose acetate butyrate as a starting material. The carboxylic groups are then introduced by treating the polymer with ozone. The disadvantage to the carboxylated cellulose esters prepared according to this method, however, is that they are not biodegradable.

10. The method referenced in paragraph 9 is exactly the method by which the carboxylated cellulose esters of Bogan et al. are prepared, i.e. cellulose acetate butyrate is reacted with ozone. Thus, the non-biodegradable cellulosic polymers of Bogan et al. are inherently different from that of the claimed invention.

11. The non-biodegradability of the polymers of Bogan et al. is also illustrated by the intended uses of their compositions. Specifically, the Bogan polymers are intended for use as pigment dispersions (Col. 17, line 44), metal coatings (Col. 18, line 34), ink compositions (Col. 20, line 51), and wood coatings (Col. 22, line 9). One skilled in the art

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would realize that such products should not be biodegradable since they must remain intact in order to exhibit permanent sealing/protective qualities.

12. The oxidized cellulose esters of the claimed invention are further distinguished from those of Bogan et al. since they do not include lactone functional groups. Bogan et al. note that their carboxylated cellulose esters including the acetates, butyrates and propionates (termed "XAE") contain a lactone level of from about 4.52×10^{-5} to about 6.13×10^{-4} moles of lactone moiety per gram of XAE. In contrast, Applicants' oxidized cellulose esters do not include lactone moieties, as evidenced by the claimed structures.

13. The Bogan et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

14. The compositions of Lee et al. also do not read on Applicants' claimed compounds since the Lee compounds are not biodegradable.

15. The non-biodegradability of the Lee et al. compounds is evidenced by the low carboxylic content of its compounds (0.14-0.3% w/w) as well as the intended uses of the compounds. More specifically, the intended uses of the Lee compounds, similar to those of Bogan et al., include coating formulations for paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets.

16. The Lee et al. compounds cannot be biodegradable if they are to be used for their intended purposes.

17. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified

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statement is directed.

Date: 7/6/04

Vijay Kumar

Dr. Vijay Kumar

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